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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,858

03/18/2004

Choong-Chin Liew

4231/2053B

8079

29933 7590 07/18/2007  
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EXAMINER
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SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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07/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/803,858

Applicant(s)

LIEW, CHOONG-CHIN

Examiner

Juliet C. Switzer

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. This office action is written in response to applicant's papers filed 4/24/07. Claims 1-8 were canceled. Claims 9-10 were amended, and claims 11-12 were added. Applicant's amendments and remarks have been carefully considered but are not sufficient to place the claims in condition for allowance for the reasons set forth in this office action. This action is **FINAL**.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 9, 10, 11, and 12 are rejected under 35 U.S.C. 102(b) and 102(a) as being anticipated by Ralph et al. (WO 98/24935, as cited in IDS), as evidenced by GenBank alignments with NM\_020362.2 and NM\_014868 and "Expression profile suggested by analysis of EST counts," for genes C1orf128 and ring finger protein 10 (RNF10) both downloaded 7/9/07.

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4. Claims 9, 10, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Ralph et al. (US 6190857, as cited in IDS), as evidenced by GenBank alignments with NM\_020362.2 and NM\_014868 and "Expression profile suggested by analysis of EST counts," for genes Clorf128 and ring finger protein 10 (RNF10) both downloaded 7/9/07.

The two Ralph et al. references have substantially identical disclosures, but are applicable to the instantly claimed invention as of different dates. Both references are applied to the instant claims. In the rejection, column and line numbers from the issued patent are used to refer to the disclosure, but each portion referenced in the patent is also present in the WO document.

Ralph et al. teach that responses secondary to disease states may be reflected in changing patterns of leukocyte mRNA levels that correlate with the presence of the disease state (Col. 5, lines 27-33). Ralph et al. teach the use of RT-PCR to identify two or more genes differentially expressed in total blood cell RNA of blood samples which have not been fractionated into cell types from subjects having a disease as compared with subjects not having said disease, wherein the disease is prostate or breast cancer. Ralph et al. exemplify this method for the detection of two transcripts referred to by Ralph et al. as UC331 and UC332, these sequences are RNA encoded by each of two genes (Example 5.6.2 and following, Col. 98). Ralph et al. teach using oligonucleotides of predetermined sequence which are primers specific to the particular transcripts to detect a presence of the RNA molecules (Col. 98, lines 17-19 and 26-27). Ralph et al. detect a presence in samples from patients having prostate or breast cancer and from healthy volunteers (Col. 98, lines 5-6). Ralph detect the presence of these RNA in DNA-free total RNA from peripheral blood (Col. 98, lines 5-6). DNA-free total RNA from peripheral blood is RNA of a blood samples which have not been fractionated into cell types. Ralph et al. quantify the

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level of RNA encoded by the genes from both patients having disease and healthy patients, using relative quantitative RT-PCR (Col. 98, line 8). Ralph et al. determine a difference between the levels of RNA in diseased and control samples (Col. 98, lines 32-37).

The UC331 and UC332 transcripts are INHERENTLY products from genes that are expressed in blood and heart tissues of a human subject not having the disease (Col. 101, lines 41-47 and Col. 102, line 5-10). Ralph et al. teaches that the UC331 transcript is given in SEQ ID NO: 29 (Col. 98, lines 55-60). This sequence is 98% identical to a molecule referred to as Homo sapiens chromosome 1 open reading frame 128 (C1orf128; see attached alignment), and this open reading frame is expressed in cardiac tissue (see expression profile suggested by analysis of EST count for C1orf128). Ralph et al. also teach that an EST of this transcript is expressed in fetal heart tissue (Table 12, Col. 97). Ralph et al. teaches that the UC332 is given in SEQ ID NO: 34 (Col. 13, line 56). This sequence is 100% identical to human ring finger protein 10 (RNF10; see attached alignment), and this mRNA is expressed in cardiac tissue (see expression profile suggested by analysis of EST count for RNF10).

Thus, the teachings of Ralph et al. anticipate independent claims 11 and 12.

With regard to claim 9, neither the specification nor the claims provide a definition of how much blood is in a “drop,” and so, any size blood sample is considered to be a drop of blood.

With regard to claim 10, Ralph et al. test blood from a human.

### **Response to Remarks**

The previously set forth rejections are all overcome by the amendment and/or cancellation of the claims. New grounds of rejection are set forth in this office action to address the amended claims.

### ***Conclusion***


5. No claim is allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday, Tuesday, or Wednesday, from 9:00 AM until 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ram Shukla can be reached by calling (571) 272-0735. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Juliet C. Switzer  
Primary Examiner  
Art Unit 1634

July 10, 2007